

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/997,623	ANDERSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chih-Min Kam	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/21/04.
2. ☒ The allowed claim(s) is/are 53-72.
3. ☒ The drawings filed on 29 November 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/978,917.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                              |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>0604</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>6/17/02</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                                      |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                              | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                |
|   | 9. <input type="checkbox"/> Other _____.   |

Art Unit: 1651

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joanne Petithory on June 30, 2004.

**Examiner's Amendments to the Specification:**

Please replace the last line on page 55 with the following line:

Ala 69.23 Å<sup>2</sup> Leu 140.76 Å<sup>2</sup>

Please delete 'http:/' at page 56, line 15.

**Examiner's Amendments to the Claims:**

Claims 53, 54, 56, 69, 70 and 71 have been amended as follows:

53. (Currently amended) A variant of a parent human protein C polypeptide, the variant comprising a sequence which

(a) differs from the parent human protein C polypeptide sequence SEQ ID NO:4 in 1 to 15 amino acid residues, and

(b) wherein the Lys residue at position 251 is substituted by an amino acid residue having a polar side chain or by an amino acid residue having opposite charge to Lys, wherein the variant in activated form exhibits an amidolytic activity.

54. (Currently amended) The variant of claim 53, wherein the activated form exhibits at least 10% of amidolytic activity of human activated protein C (APC) when tested in the APC Amidolytic activity.

In claim 56, at line 2, delete "Gly,".

In claim 69, at line 1, before "composition" insert -- pharmaceutical --.

70. (Currently amended) A method for preparing a variant of a parent human protein C polypeptide, the method comprising:

- providing a culture comprising a host cell, which comprises an expression vector comprising a nucleotide sequence encoding the variant;
- culturing the cell under conditions sufficient for expression of the variant; and
- isolating the variant from the culture,

wherein the variant comprises a sequence which

- (a) differs from the parent human protein C polypeptide sequence SEQ ID NO:4 in 1 to 15 amino acid residues, and

- (b) wherein the Lys residue at position 251 is substituted by an amino acid residue having a polar side chain or by an amino acid residue having opposite charge to Lys, and wherein the variant in activated form exhibits an amidolytic activity.

71. (Currently amended) A method for preparing a variant of a parent human protein C polypeptide in activated form, the method comprising:

- providing a culture comprising a host cell, which comprises an expression vector comprising a nucleotide sequence encoding the variant;
- culturing the cell under conditions sufficient for expression of the variant;
- isolating the variant from the culture; and
- incubating the variant under conditions sufficient to activate the variant, thereby preparing the variant in activated form,

wherein the variant comprises a sequence which

- (a) differs from the parent human protein C polypeptide sequence SEQ ID NO:4 in 1 to 15 amino acid residues, and

- (b) wherein the Lys residue at position 251 is substituted by an amino acid residue having a polar side chain or by an amino acid residue having opposite charge to Lys, and wherein the variant in activated form exhibits an amidolytic activity.

Claims 53-72 are allowed.

Art Unit: 1651

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

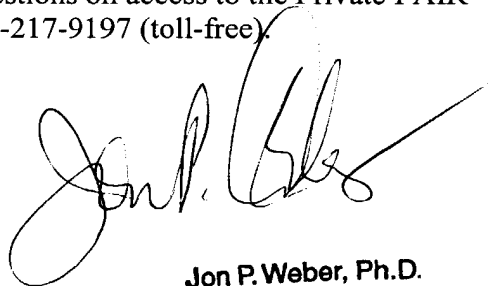
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK  
June 30, 2004

A handwritten signature in black ink, appearing to read 'Jon P. Weber', with a long, sweeping horizontal line extending to the right.

Jon P. Weber, Ph.D.  
Primary Examiner